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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,475	12/04/2003	Bertrand Castro	IVD 1072-3	6231

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EXAMINER

ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/727,475	Applicant(s) CASTRO ET AL.	
	Examiner Binta M. Robinson	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
 4a) Of the above claim(s) 18-20 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 17 and 21 is/are rejected.
- 7) ☒ Claim(s) 14-16 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09857882.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/4/03</u> . | 6) <input type="checkbox"/> Other: ____. |

Detailed Action

Claims 18, 19, 20, and 22 are withdrawn from examination because they are drawn to nonstatutory subject matter.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 –4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Camus et. al. (See Reference A). Camus et. al. teaches the instant compound, 3-carboxyethyl-3-(3,4-dichlorophenyl)-2,6-dioxo piperidine. At column 9, lines 17-18, see compound, 3-carboxyethyl-3-(3,4-dichlorophenyl)-2,6-dioxo piperidine. The difference between the prior art compound and the instantly claimed compounds is R1 moiety in the compound. In the instant compound, the R1 moiety is C1-C4 alkyl. In the Camus compound, the R1 moiety is H. The instant compound is an ester of the Camus compound. The claimed esters are structurally obvious over the free acids of the Camus compounds, see *In re Schaub* 190 USPQ 324.

It would have been obvious for one of ordinary skill in the art to modify the free carboxylic acid portion of the R1 moiety into a lower alkyl ester moiety. Therefore, the instant compounds are *prima facie* obvious in the absence of unexpected results.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Camus et. al. (See Reference A). Camus et. al. teaches the instant compound, of formula II a, where Alk is CH₂, and Ar is 3, 4-dichlorophenyl. At column 11, lines 46-47, see compound, formula IIa. The difference between the prior art compound and the instantly claimed compounds is the claiming of a diester of the compound vs. a monoester of the compound. The Camus compound is a diester of the monoester Camus compound, which has a free carboxylic acid moiety in the compound. The claimed esters are structurally obvious over the free acid of the Camus compounds, see In re Schaub 190 USPQ 324.

It would have been obvious for one of ordinary skill in the art to modify one of the carboxylic acid portion of Camus compound to obtain the instant diester. Therefore, the instant compounds are prima facie obvious in the absence of unexpected results.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Camus. (See Reference A).

Camus et. al. teaches the instant compound as shown in Formula III, where Ar is phenyl substituted two times with halogen, X is ethylene, and Y is carboxy group. At

column 3, line 45, see the compound of formula III and the radicals defined. The difference between the prior art compound and the instantly claimed compounds is the teaching of a generic compound versus a disclosed species. It would have been obvious to one of ordinary skill in the art to select various known radicals within a genus to prepare structurally similar compounds. For instance, see the example 1 at column 13, where a disclosed species is exemplified. Accordingly, the compounds are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds over those of the generic prior art compounds.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, 9, 10, 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 4, line 2, page 24, the phrase "as defined for (I) in claim 1" is indefinite because radicals R1 and X are not defined at claim 4. This rejection can be overcome by defining radicals R1 and X at claim 4.

B. Claim 5, line 5, page 24, the phrase "X is as defined for (I) in Claim 1" is indefinite because radical X is not defined at claim 5. All radicals must be defined at the claim. This rejection can be overcome by defining radical X at claim 5.

C. Claim 9, line 2, page 26, the phrase "R1 and X are as defined for (I) in claim 1" is indefinite, since all radicals must be defined at claim 9. This rejection can be overcome by defining radicals, R1 and X at claim 9.

D. Claim 17, line 2, page 28, the phrase "R1 and X are as defined for (I) in claim 1" is indefinite, since all radicals must be defined at claim 17. This rejection can be overcome by defining radicals, R1 and X at claim 17.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 1 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6469173. This is a double patenting rejection.

Claim 2 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 2 of prior U.S. Patent No. 6469173. This is a double patenting rejection.

Claim 3 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 3 of prior U.S. Patent No. 6469173. This is a double patenting rejection.

Claim 4 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 4 of prior U.S. Patent No. 6469173. This is a double patenting rejection.

Claim 9 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 6 of prior U.S. Patent No. 6469173. This is a double patenting rejection.

Claim 10 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 7 of prior U.S. Patent No. 6469173. This is a double patenting rejection.

Claim 11 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 8 of prior U.S. Patent No. 6469173. This is a double patenting rejection.

Claim 12 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 9 of prior U.S. Patent No. 6469173. This is a double patenting rejection.

Claim 13 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 10 of prior U.S. Patent No. 6469173. This is a double patenting rejection.

Claim 5 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 5 of prior U.S. Patent No. 6469173. This is a double patenting rejection.

Claim 6 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6686182. This is a double patenting rejection.

Claim 7 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 2 of prior U.S. Patent No. 6686182. This is a double patenting rejection.

Claim 8 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 3 of prior U.S. Patent No. 6686182. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 5 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of US Patent 6469173. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 5 anticipates the generic process in the instant claim 5.

Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-12 of US Patent No. 6469173. Although the conflicting claims are not identical, they are not patentably distinct from each other because the 6469173 compounds anticipate the instant genus of compounds.

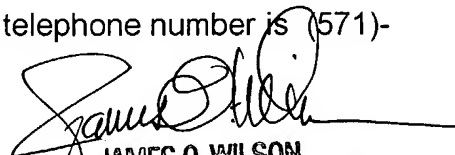
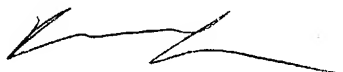
Claims 14-16 are objected to for being based on a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1600.



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600